



Applicant: Wisniewski et al.  
Serial No.: 10/056,237  
Filed: January 25, 2002  
Docket No. 2035.749  
*AF ZJW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** Wisniewski et al.

**Group Art Unit:** 3753

**Serial No.:** 10/056,237

**Examiner:** John K. Ford

**Filed:** January 25, 2002

**Appeal No.:**

**Title:** FREEZING AND THAWING OF BIOPHARMACEUTICALS WITHIN A VESSEL HAVING A DUAL FLOW CONDUIT

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 11, 2005.



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Date of Signature: April 11, 2005

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Commissioner for Patents  
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**REPLY TO EXAMINER'S ANSWER BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Dear Sir:

This is a reply under 37 CFR § 1.193 from an Examiner's Answer dated February 9, 2005. Therefore, this Reply Brief is timely filed within two months, i.e., by April 12, 2005 under 37 C.F.R. §1.7(a).

## **ARGUMENT**

This is a reply under 37 CFR § 1.193 from an Examiner's Answer dated February 9, 2005. Therefore, this Reply Brief is timely filed within two months, i.e., by April 9, 2005.

## **ARGUMENT**

This paper relates to the Grounds Of Rejection and Response to Argument sections of the Examiner's Answer, dated February 9, 2005, which is incorporated herein by reference. The points raised in the Examiner's Answer are addressed below, in the order in which they appear.

### **1. "Biopharmaceutical Product"**

Appellant acknowledges the Examiner's withdrawal of the rejection directed to the term "biopharmaceutical product." However, Appellant respectfully notes that the explanation on page 7 of its Appeal Brief is a repetition of the same argument provided on pages 8 and 9 in a Response to Office Action, dated April 14, 2003. Therefore, the Examiner's statement that "Appellant has explained clearly [why buffers should be included in the definition of "biopharmaceutical products"] for the first time" is misplaced.

### **2. Alleged Improper Combinations of References**

As set forth in the Brief of Appellant, there is no motivation or suggestion to combine the cited references because each reference freezes products by completely different ways using completely different freezing principles. For example, the 1992 Wisniewski and Wu publication teaches cooling the outside and inside of the cylinder, the 1986 Kalhori and Ramadyani article teaches heating the medium from the outside of the cylinder while the structure within was cooling it and the '642 West patent discloses a completely different method of freezing from the previous two references.

The Examiner over simplifies the motivation to combine references asserted in the Office Action and ignores the problems in processing biopharmaceutical materials recognized by Applicants in the specification (see paragraph 32), which was supported by declarations of four

people of ordinary skill in the art. Instead, the Examiner combines two references on the sole basis that both devices disclosed therein freeze products – nothing more. However, the Examiner has not and cannot point to anything in the references to support the substitution of the structure in the 1986 Kalhori and Ramadhyani for the structure in the 1992 Wisniewski and Wu prior art, or any motivation to do the same. Simply because one reference is cited in the appendix of another reference is insufficient, alone, to support the Examiner’s position. In reality, the Examiner improperly combines the two references based on an “obvious to try” basis, without pointing to any suggestion, motivation or disclosure in the references themselves to support such a combination.

The Examiner attempts to point to three motivational reasons in the final rejection to combine these references, namely (1) to improve heat transfer; (2) to facilitate ease of construction; and (3) to facilitate easy removal of the frozen mass. However, the Examiner does not point to anything in any of the cited references that suggest or disclose the combination of these references to achieve these results. All three of these reasons are merely conclusions using Appellant’s disclosure as a guide. The fact that the 1986 Kalhori and Ramadhyani article discloses a device having “superior heat transfer characteristics” does not provide motivation or suggestion to replace the centrally mounted heat exchanger and fins of the 1992 Wisniewski and Wu publication with the heat exchanger and fins shown in the 1986 Kalhori and Ramadhyani article, especially in light of the fact that one teaches heating the outside of the device while the other teaches cooling from the outside. Instead, it is only with impermissible hindsight reasoning of applicants’ invention that the cited references have been combined in an attempt to support an obviousness rejection of the independent claims. Such hindsight reasoning is improper.

The Examiner wants the Board to completely ignore five declarations from persons of ordinary skill in the art in the field concerning the processing concerns of biopharmaceutical products. The Examiner simply characterizes this evidence as “self-serving at its core”, without providing any evidence of his own to contradict statements made by those skilled in the art. Aside from the Examiner’s own self-serving statements, these declarations are uncontested. In fact, the Examiner repeatedly ignored Appellant’s request during prosecution that the Office show, in contradiction to the declarations submitted by Appellant, that products such as orange

juice, milk and comestibles<sup>1</sup> require uniform freezing at a rapid pace to prevent damage, as recognized by Appellant in the present application relative to the processing of biopharmaceutical products. In response, the Examiner repeatedly asserted his own personal, unsupported opinions based his masters degree in engineering on this issue in the Office Actions. Even in his Answer, the Examiner asserted “it is well known in the heat transfer art that scientists routinely make heat transfer measurements in one material that can be extrapolated to other materials by known correlations, such as Reynolds number, Prandtl number and Nusselt number.” However, he provides no support for this alleged “well known” fact. More importantly, he provides no explanation of how this relates to the problem addressed by the present invention and supported by the declarations of those skilled in the art for the need to preserve biopharmaceutical products to prevent damage as compared to other non-biopharmaceutical products, such as orange juice, milk and comestibles, not to mention how these products fall within the approved meaning of the term “biopharmaceutical products”. Moreover, he makes a number of unsupported statements in his Answer that “much of [the] prior art related to freezing of food products appears in the Appendices of the 1996 Wisniewski and Wu prior art – which isn’t true, and that “much of the prior art relied upon in the rejection discusses the problems of attaining uniform freezing of liquid food products” – which also is untrue.

Appellant has asserted throughout prosecution that the 1992 Wisniewski and Wu article accurately depicts the prior art device (“Genentech device”) to the best of Mr. Wisniewski’s memory. The applicants disclosed this article during prosecution and, in an effort to assist the Examiner understand the same, and provided declarations to offer the best explanation of the Genentech device. However, despite these efforts, the Examiner continued to request that Appellant contact Genentech and test the actual Genentech device, which is completely absurd. Appellant’s failure to contact a competitor/customer concerning a device that was disclosed and accurately depicted in an article published over a decade ago has caused an unexplained

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<sup>1</sup> The Examiner’s suggestion that Appellants produced art for consideration during prosecution related to the freezing of food products because they considered them to be “related” is improper. The modification of the language of 37 CFR 1.56 in 1992 emphasized that there is a duty of candor and good faith that is broader than the duty to disclose material information. MPEP 2001.04. In fact, the Patent Office continued to expect that applicants would continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. Id. Clearly, the submission of any prior art reference during prosecution for consideration by the Office is not an admission by an applicant that the references are material.

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animosity towards Appellant, resulting in an unnecessary prolonged prosecution of this application.

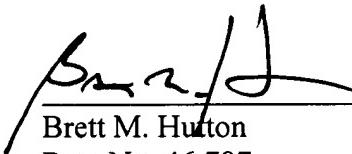
Appellant never admitted in the Appeal Brief that no human being can accurately predict the temperature profiles of the devices disclosed in the references. Instead, Appellant argued that, if the Examiner truly believed that a computer is required to predict temperature profiles, how can he support a rejection based on an obvious combination of the references.

### CONCLUSION

For the reasons set forth above and in the initial Brief of Appellants, reversal of the rejections and allowance of this application are respectfully requested.

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Respectfully submitted,



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